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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,375	01/23/2004	Arnold Stan Lippa	10596-016-999	9972
20583	7590	04/11/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			SOLOLA, TAOFIQ A	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 04/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/764,375

Applicant(s)

LIPPA ET AL

Examiner

Taofiq A. Solola

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 28 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 53-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 53-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 53-56 are pending in this application.

Claims 1-52 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 21, lines 4-5, the specification discloses hexane: isopropyl (95:5) and diethylamine (0.05 %) as the eluent. There is no disclosure that any and/all organics are applicable as eluents in the instant process. The organic eluent is a critical element of the invention and must be fully disclosed. Therefore, the specification lacks adequate support for claims 53-56. Applicant must show possession of the invention by describing it with all the claimed limitations. *Lookwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed Cir. 1997). By limiting the eluent to hexane: isopropyl (95:5) and diethylamine (0.05 %) the rejection would be overcome.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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Claims 53-56, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "eluent", line 3, claim 53 and line 3, claim 55, is a critical element of the invention and must be fully disclosed. Also, claims 54 and 56 fails to recite how the "concentration" is performed. Therefore, claims 53-56 are indefinite. In patent examination, it is essential for claims to be precise, clear, correct, and unambiguous. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). By limiting the eluent to hexane: isopropyl (95:5) and diethylamine (0.05 %) and add how the compound is concentrated the rejection would be overcome.

Applicant's arguments filed 2/28/05 have been fully considered but they are not persuasive. Applicant argues that the term "organic eluent" is used throughout the specification in its ordinary and customary meaning. This is not persuasive because ordinary and customary meaning is not the basis of patentability of the instantly claimed process. The specification fails to provide conclusive evidence that any organic eluent is applicable in the instant process and does not define the specific organic eluents that are applicable. Applicant further contends that in page 7, starting from line 41, there are preferred eluents. The term "preferred" or "preferably" implies the quoted eluents are examples only. "Exemplification is not an explicit definition." Claim Interpretation, 2004. The specification must set forth any definition explicitly with reasonable clarity, precision and deliberateness, *Teflex Inc. v. Ficosa North Ame. Corp.*, 63 USPQ2d 1374 1381 (Fed Cir 2001). Also, to say all known organic eluents have the same utilities (applicable in the instant process) is not credible. See MPEP 2107. Even then, the examples cited in the specification, *ibid*, are referred to as "hydrocarbon solvent". The term

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"hydrocarbon" embraces the entire textbook of organic chemistry and does not sufficiently identify the eluents.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. J. Chrom. A, (1999) Vol. 865, pages 211-226.

Applicant claims a process for separating racemic mixture of -1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane with chiral polysaccharide stationary phase and an organic eluent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Miller et al., teach a process for separating racemic mixture with chiral polysaccharide stationary phase and polar organic solvents as organic eluent. Miller et al., teach several examples of compounds which could be separated with their process.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of Miller et al., is that applicant separates racemic mixture of -1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane instead of "racemates compounds" by Miller et al.

Finding of prima facie obviousness---rational and motivation (MPEP §2142.2413)

However, Miller et al., teach that polar organic solvents with polysaccharide stationary phase are useful for separating racemic mixtures, and the term racemates embraces the racemate mixture of -1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane. Miller et al., also teach

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advantages of using the process to separate racemates, which would provide motivation to apply the process in any racemates. See the abstract, introduction, materials and conclusion.

Therefore, the instant invention is prima facie obvious from the teaching of Miller et al. One of ordinary skill in the art would have known to separate racemate mixture of –1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane with polar organic solvents and polysaccharide stationary phase at the time the invention was made. The motivation is from the teaching of Miller et al., that polar organic solvents with polysaccharide stationary phase are useful for separating racemic mixtures and the advantages thereof.

Applicant's arguments filed 2/28/05 have been fully considered but they are not persuasive. Applicant argues that, according to the Office, the process of Miller et al., must meet a standard applicable to any and all racemates compounds. This may not be true for any and all racemates but it is true for applicant's racemates as confirmed by applicant's invention. Otherwise, the process of Miller et al., would not have separated applicant's racemates. The fact that the process of Miller et al., is applicable for separating applicant's racemates implies applicant's compound is analogous to that of Miller et al. Applicant should note that the use of analogous starting material in a well-known process is prima facie obvious. *In re Durden*, 226 USPQ 359 (1985).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.


TAOFIQ SOLOLA
PRIMARY EXAMINER
Group 1626

April 4, 2005